BACKGROUND ON MEDICAL ERROR REPORTING

History of Medical Error Reporting

Reports on medical errors can be traced back to the 1970's, when a physician-attorney named Don Mills analyzed more than 20,000 medical charts concluding that one patient in twenty was harmed by treatment.[1] A body of research describing the problem of medical errors began to emerge in the early 1990s with landmark research conducted by Leape, and supported by the Agency for Health Care Policy and Research, now the Agency for Healthcare Research and Quality.[2]

The Institute of Medicine of the National Academy of Sciences

The Institute of Medicine was chartered in 1970 as a component of the National Academy of Sciences in Washington, DC. It is a nonprofit organization providing evidence-based analysis and guidance on matters of biomedical science, medicine, and health.[3]

In 1998 the Institute of Medicine appointed the Committee on the Quality of Health Care in America to identify strategies for achieving a substantial improvement in the quality of healthcare delivered to Americans. In 1999 the Institute of Medicine published a landmark report on medical errors entitled *To Err Is Human: Building a Safer Health Care System*.[4] The report estimated that between 44,000 and 98,000 patients die each year as a result of medical errors. The report estimated that a medication error occurs for two of every one hundred patients admitted to a hospital. The report further estimated that the total cost of preventable medical errors to be between 17 and 29 billion dollars per year.[5]

The 1999 Institute of Medicine report significantly increased awareness of medical errors and brought attention to the need for reliable data on the number of medical errors occurring in health care facilities. A subsequent Institute of Medicine report, *Crossing the Quality Chasm: A New Health System for the 21st Century*, reinforced the need for reliable data and cited the need for evidence-based policies and practices.[6]

The Institute of Medicine report cited several causes of medical errors including the following:[7]

- Lack of reliable data on the number of medical errors which limits the ability to identify origins of the problem and develop initiatives to resolve the problem

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[1] D.H. Mills, *Medical Injury Information: A Preparation for Analysis and Implementation of Prevention Programs*, 236(4) Journal of the American Medical Association, pp. 379-381 (1976).
[2] Agency for Healthcare Research and Quality, *Medical Errors: The Scope of the Problem* (2000), Retrieved February 17, 2007 from http://www.ahrq.gov/qual/errback.htm.
[3] Institute of Medicine of the National Academies, Retrieved February 12, 2007 from http://www.iom.edu/CMS/AboutIOM.aspx.
[4] Institute of Medicine, *To Err Is Human: Building A Safer Health System* (Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, eds., National Academy Press, 1999).
[5] *Id.*
[6] Institute of Medicine, Crossing the Quality Chasm: A New Health System for the 21st Century (National Academy Press, 2001).
[7] Institute of Medicine, *To Err Is Human: Building A Safer Health System* (Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, eds., National Academy Press, 1999).

- Medical errors are often a system failure where care practices are inconsistent between healthcare professionals leading to mistakes
- With larger, decentralized, and fragmented health care facilities and an increase in the number of health professionals providing care to a patient, there is an increased potential for medical errors
- Access to patient information by health care providers
- Lack of legible handwriting or conversely data entry mistakes
- Use of acronyms or abbreviations
- Inadequate documentation
- Patient loads placed on staff resulting in timing issues in the delivery of care
- Competition between facilities resulting in the lack of development of communication systems between health care providers

The National Quality Forum

In a 1998 report, the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry proposed creation of the National Quality Forum as part of an integrated national quality improvement agenda. The National Quality Forum was incorporated as a new organization in May 1999. The mission of the National Quality Forum is to improve the quality of American healthcare by setting national priorities and goals for performance improvement, endorsing national consensus standards for measuring and publicly reporting on performance, and promoting the attainment of national goals through education and outreach programs.[8]

The National Quality Forum is a not-for-profit membership organization created to develop and implement a national strategy for healthcare quality measurement and reporting. The National Quality Forum, a public-private partnership, is made up of all parts of the healthcare system, including national, state, regional, and local groups representing consumers, public and private purchasers, employers, healthcare professionals, provider organizations, health plans, accrediting bodies, labor unions, supporting industries, and organizations involved in healthcare research or quality improvement.[9]

In 2002, the National Quality Forum published a report titled *Serious Reportable Events in Healthcare*. The report identified twenty-seven (27) events that are serious, largely preventable, and of concern to both the public and health care providers. The report recommended that these twenty-seven events be reported by all licensed health care facilities. The National Quality Forum suggested that analysis of reported events could provide caregivers and patients with important information about the safety of healthcare and opportunities for improvement.[10]

Indiana's Medical Error Reporting System is based on the National Quality Forum's twenty-seven serious reportable events. Indiana added language to clarify a few of the events and added definitions of terms to provide further clarification. Indiana is the second state to develop a medical error reporting system based on the National Quality Forum serious adverse reportable events. In 2003, Minnesota became the first state to institute a mandatory health event reporting system. Like Minnesota's system, the Indiana Medical Error Reporting System has been a

[8] National Quality Forum, http://Qualityforum.org/about/mission.asp.
[9] *Id.*
[10] *Serious Reportable Events in Healthcare*, National Quality Forum (2002).

collaborative effort with strong support from Indiana's healthcare community and a shared goal of improving patient safety.

Medical Error Reporting Systems

The National Academy for State Health Policy reported that, as of September 2005, twenty-four (24) states have passed legislation or regulations related to hospital reporting of adverse events. Twenty-three (23) are mandatory systems with one voluntary system. The National Academy reported that although the overriding reason for many of the reporting systems was to ensure accountability, many state reporting systems have a learning component.[11]

The National Academy reported that the outcomes of reporting systems have varied. Reporting systems have the potential to improve patient safety through event report analysis and dissemination of best practices and lessons learned to prevent event recurrences. Some states send out safety alerts when incidents with significant consequences are reported. Other states attempt to aggregate data to identify patterns and trends across facilities. Newsletters highlight trends and showcase best practices to reduce incidents. Some states provide facilities with a comparison of their data with that of peer facilities or national standards. Other states produce routine reports showing trends in reportable events.[12]

Patient Safety and Quality Improvement Act of 2005

An emerging trend has been the development of patient safety centers. These centers are public or private entities that conduct activities designed to improve patient safety and the quality of healthcare delivery.

The Patient Safety and Quality Improvement Act of 2005 (109th Congress, 1st Session, Senate Bill 544) allows for certification of patient safety organizations that collect and analyze patient safety information for the purposes of encouraging a culture of safety and providing feedback and assistance to effectively minimize patient risk. Federal regulations enabling the certification of patient safety centers are pending. Additional information on these centers may be found in a report by the National Academy for State Health Policy.[13]

Patient safety centers have the potential to be important leaders in addressing medical errors and adverse events. Medical errors and adverse events are generally system-based problems. The solutions must also be system-based. Subject matter experts at Indiana colleges and universities are needed to study issues and develop evidence-based strategies for addressing care issues. Health policy organizations are needed to evaluate health care policies and develop best practices that promote consistent care practices between providers. Health provider associations are needed to coordinate information between providers and implement quality care initiatives. Patient safety centers serve the important role of coordinating these activities and ensuring that issues are addressed in a timely, evidence-based, and effective manner.

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[11] Jill Rosenthal and Maureen Booth, *Maximizing the Use of State Adverse Event Data to Improve Patient Safety*, National Academy for State Health Policy (October 2005), page 4.
[12] *Id.*
[13] Jill Rosenthal and Maureen Booth, *State Patient Safety Centers: A new approach to promote patient safety*, National Academy for State Health Policy (October 2004).